FDA 510(k) Premarket Notification

CLEARED

K211871 FAICO Dental Implant System and CAD/CAM Abutments

Nov 18, 2021
154 days to decision

K211871 · Product code: **NHA** · Dental
Source: https://www.510kdatabase.net/k211871/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Abutment, Implant, Dental, Endosseous (NHA)
Date received	Jun 17, 2021
Decision date	Nov 18, 2021
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Faico Medical, LLC**
Location	Boca Raton, FL, US
Contact	Hernan Dario Fernandez
510(k) history	3 submissions · 3 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	**Arazy Group**
Contact	Raymond Kelly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov